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| <b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>  |  | Docket Number (Optional)<br>030906 |
| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]<br>on <u>April 14, 2006</u> | Application Number<br>09/987,763         | Filed<br>November 15, 2001         |
| Signature _____   | First Named Inventor<br>Corey M. Crafton |                                    |
| Typed or printed name <u>Maria N. Dupain</u>  | Art Unit<br>1633                         | Examiner<br>Sumesh Kaushal         |

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

applicant/inventor.

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

attorney or agent of record.

Registration number 54,468

Signature

Duane A. Stewart III

Typed or printed name

412-562-1622

Telephone number

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

April 14, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.  
Submit multiple forms if more than one signature is required, see below\*.



\*Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Attorney Docket No.: 030906

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Crafton, Corey M. et al. : Examiner: Kaushal, Sumesh

Serial No.: 09/987,763 : Art Unit: 1633

Filing Date: November 15, 2001 :

Entitled: NUCLEOTIDE SEQUENCES FOR TRANSCRIPTIONAL REGULATION OF  
CORYNEBACTERIUM GLUTAMICUM

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

MAIL STOP AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

This paper is filed pursuant to the July 12, 2005 Notice in the Official Gazette entitled "New Pre-Appeal Brief Conference Pilot Program" and in accordance with the subsequent Notice of January 10, 2006 extending the pilot pre-appeal brief conference program until further notice. This paper is filed with a Notice of Appeal that is believed timely with a Petition for Extension of Time of one month. If further extensions are necessary to make this Request timely, kindly grant them and charge the fee for same to Deposit Account No. 02-4800, in the name of Buchanan Ingersoll PC.

Claims 1, 2, 4-21 and 25-38 are pending and stand rejected under 35 U.S.C. § 101 for alleged lack of either a specific asserted utility or a well-established utility. Those claims also stand rejected under 35 U.S.C. § 112, first paragraph for alleged failure to show a person skilled

in the art how to make and use the invention. The § 112 rejection is tied to the § 101 rejection, and both will be addressed simultaneously in this request.

Applicants submit that the prior Office Actions have failed to set forth a proper *prima facie* case of lack of utility. Furthermore, Applicants submit that the alleged *prima facie* case of lack of utility has been overcome by argument and evidence submitted by the Applicants.

I. Prima Facie Case

Applicants respectfully submit that no *prima facie* case of lack of utility has been established in this case. Establishment of a *prima facie* case of lack of utility requires consideration of all asserted utilities in an application, and only one credible assertion of utility for the invention is necessary.

No Office Action has considered all of the utilities suggested in the specification. In particular, there has been no consideration of utility resulting from the increased expression of β-galactosidase under the transcriptional control of SEQ ID NO:7. If this utility were considered and accepted, then the utility rejection would be removed. Applicants' arguments in this regard are set forth more fully in prosecution. In particular, Applicants direct the panel to the argument beginning on page 8 of the Response to Final Office Action filed on May 24, 2005.

II. Specific and Substantial Utility

Applicants maintain that no *prima facie* case of lack of utility has been made in an Office Action; therefore, no showing of specific and substantial utility must be made by the Applicants. In the event that Applicants' arguments in that respect are not accepted, and to advance prosecution, Applicants also present the following information on the specific and substantial utility present in this case.

Applicants maintain that the claims have both a well-established utility and a specific asserted utility. Both evidence and argument to this affect have been provided in detail during prosecution of this application. In particular, Applicants direct the attention of the panel to the argument on pages 10-14 of the Response to Final Office Action filed on May 24, 2005, as well as the Declaration of Ms. Corey M. Crafton filed with the Supplemental Response to Final Office Action dated March 8, 2006.

The Applicants have provided argument and evidence based on the specification and on knowledge available to those skilled in the art showing that both a well-established utility and a specific asserted utility exist. As demonstrated in Table 1a of the specification, a polynucleotide including the nucleotide sequence set forth in SEQ ID NO:7 may be regulated by pyruvate homology of a *Corynebacterium ldh* gene including the nucleotide sequence of SEQ ID NO:7 was determined by homology comparisons with genes from other organisms including *E.coli* and *B. subtilis*. This point is further buttressed by the sequence homologies to other *Corynebacteria* sequences that have been determined since the filing of the application as set forth in page 3 of Ms. Crafton's Declaration.

Ms. Crafton's Declaration also includes evidence regarding existence of the Pribnow Box in the claimed sequence, as well as evidence regarding length of the claim sequence and a comparison to other similar sequences. This information would be interpreted by one skilled in the art as indicating that this sequence would be useful for the claimed and described purposes.

Finally, Applicants must stress that the increased  $\beta$ -galactosidase activity resulting from use of the claimed promoter, as discussed in Example 9 of the application and further discussed by Ms. Crafton on page 3 of her Declaration, is highly and definitively probative of utility of the structures provided and claimed in this application. As Ms. Crafton states on page 3, item 6 of

her Declaration, “[T]his increased activity is indicative of promoter activity because increased  $\beta$ -galactosidase activity is a conventionally used indicator of promoter activity in bacteria and fungi.” Ms. Crafton’s Declaration further includes citations to references demonstrating the utility of increased  $\beta$ -galactosidase activity as recognized by one skilled in the art.

### Conclusion

The Applicants have demonstrated, both by argument and by evidence throughout prosecution, that the Office Actions have not presented a proper *prima facie* case of lack of utility. Furthermore, Applicants have demonstrated, by argument and evidence, that the alleged *prima facie* case of lack of utility has been adequately rebutted and the rejection for lack of utility should be withdrawn.

Reconsideration and allowance of all claims is respectfully requested.

Respectfully submitted,



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Date: April 14, 2006



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| IN RE APPLICATION OF:<br><br>Corey M. Crafton et al.   |                                       |
| Application Serial No.:<br><br>09/987,763  | Filing Date:<br><br>November 15, 2001 |
| Title:<br><br>Nucleotide Sequences for Transcriptional Regulation of<br>Corynebacterium Glutamicum |                                       |
| Confirmation No.<br><br>7167   | Examiner:<br><br>Sumesh Kaushal       |

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Date of Deposit: April 14, 2006

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Maria N. Dupain  
(Typed or printed name of person mailing paper or fee)

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(Signature of person mailing paper or fee)